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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,750	12/09/2002	Wilhelm Tischer	HURR-1205	6008
24972	7590	10/03/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/049,750	TISCHER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,27,33,44 and 46-94 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,27,33,44 and 46-94 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 1, 27, 33, 44 and 46-94 are pending.

Applicant's preliminary amendment canceling claims 3-25, 28-31, 34-36, and 39-41 filed on 12/9/2002 is acknowledged.

Applicant's preliminary amendment canceling claims 2, 26, 32, 37, 38, 42-43, 45 and addition of claims 47-95 filed on 7/10/2003 is acknowledged. It is noted that claims 47-95 have been renumbered 46-94 according to 37 CFR 1.126 since no claim 46 is of record.

It is noted that while Applicant's remarks (page 7) as set forth in a communication filed on 7/10/2003 state that claims 1, 27, 33, 46 and 47-95 are pending, the Examiner has not been able to find a preliminary amendment canceling claim 44. Since it is unclear if claim 44 has been canceled, the Examiner has assumed that claim 44 is still pending. Clarification is required.

It is noted that claim 44 is directed to a use, which is non-statutory matter (neither a method or a product). For restriction purposes, claim 44 will be assumed as being directed to a method of use of a polypeptide having deoxyribokinase activity for enzymatic synthesis of deoxyribonucleosides.

Claims 27 and 33 are dependent on canceled claims. For restriction purposes, it will be assumed that both claims depend on claim 1. Claims depending on claims 27 and 33 which recite limitations lacking antecedent basis will be included in the restriction groups. The Examiner will determine the applicability of the recited limitations to the subject matter of a particular group and will place those claims in the groups accordingly.

Claim 69 (as renumbered) refers to SEQ ID NO: 11 as the amino acid sequence of a deoxyribokinase whereas claim 74 (as renumbered) refers to SEQ ID NO: 11 as the amino acid sequence of a deoxyribosyl transferase. The Examiner performed a cursory search through the sequence listing and found that SEQ ID NO: 11 correspond to a nucleotide sequence of a *Salmonella typhi* protein. For

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restriction purposes, it will be assumed that the deoxyribokinase of claim 69 (as renumbered) comprises SEQ ID NO: 12 and the deoxyribosyl transferase of claim 74 (as renumbered) comprises SEQ ID NO: 14.

Claim 92 (as renumbered) refers to the isolation of a polypeptide having NdT activity, however, claim 70 (as renumbered) from which it depends encompasses a method which appears to be unrelated to a method wherein a polypeptide having NdT activity can be isolated. For restriction purposes, the examiner has interpreted claim 92 (as renumbered) to depend on claim 91 (as renumbered).

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 27, 33, 44, 46-60, 67-75, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a thymidine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from phosphorylation of deoxyribose by a deoxyribokinase (dRK) comprising SEQ ID NO: 12, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group II, claim(s) 1, 27, 33, 44, 46-60, 67-75, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a purine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from phosphorylation of deoxyribose by a deoxyribokinase (dRK) comprising SEQ ID NO: 12, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group III, claim(s) 1, 27, 33, 46-60, 61-64, 70-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a thymidine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from FDP, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

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Group IV, claim(s) 1, 27, 33, 46-60, 61-64, 70-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a purine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from FDP, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group V, claim(s) 1, 27, 33, 46-60, 61-63, 66, 70-78, 80, 82-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a thymidine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from GP and oxygen, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group VI, claim(s) 1, 27, 33, 46-60, 61-63, 66, 70-78, 80, 82-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a purine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from GP and oxygen, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group VII, claim(s) 1, 27, 33, 46-60, 61-63, 65, 70-78, 80, 82-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a thymidine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from DHA and ATP, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group VIII, claim(s) 1, 27, 33, 46-60, 61-63, 65, 70-78, 80, 82-85, drawn in part to a method for *in vitro* synthesis of deoxyribonucleosides from deoxyribose-1-phosphate (dR1P) and a nucleobase wherein said synthesis is catalyzed by a purine phosphorylase, wherein dR1P is formed from dR5P, wherein dR5P is obtained from condensation of GAP with acetaldehyde, wherein GAP is generated from DHA and ATP, and wherein said deoxyribonucleosides are further reacted with a second nucleobase in a reaction catalyzed by a deoxyribosyl transferase (NdT) comprising SEQ ID NO: 14.

Group IX, claim(s) 86-92, drawn to a method for preparing an enzyme for an *in vitro* method for the enzymatic synthesis of a deoxyribonucleoside, wherein said method comprise reacting an isolated nucleic acid comprising SEQ ID NO: 13 with a deoxyribonucleoside containing a nucleobase, and wherein said deoxyribonucleoside containing a nucleobase is further reacted with a second nucleobase.

Group X, claim(s) 93, drawn to a method for preparing an enzyme for an *in vitro* method for the enzymatic synthesis of a deoxyribonucleoside, wherein said method comprise reacting an isolated nucleic acid comprising SEQ ID NO: 11 with a deoxyribonucleoside containing a nucleobase, and wherein said deoxyribonucleoside containing a nucleobase is further reacted with a second nucleobase.

Group XI, claim(s) 94, drawn to a method for synthesizing deoxyribonucleosides *in vitro* comprising contacting a mixture containing deoxyribose with phosphate in the presence of an enzyme having NdT activity to form dR5P.

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2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions listed as Groups I-XI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking Groups I-XI is a method to produce nucleosides using nucleoside phosphorylases, which is shown by Yamauchi et al. (EP 0411158 B1, published May 1996; cited in the IDS) to lack novelty or inventive step since Yamauchi et al. teach a process for the production of nucleosides using pyrimidine and purine phosphorylases wherein several substrates are used including deoxyribose-1-phosphate (page 10, lines 14-20). Thus, the technical feature linking Groups I-XI does not make a contribution over the prior art and the claimed inventions do not meet the requirement of unity of invention under PCT Rule 13.2.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

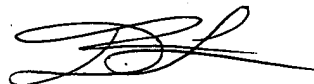
6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

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Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
September 26, 2005